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REMARKS

Claims 59-80 are pending in this application. Claims 59, 64, 65 and 77-80 are amended herein for clarity. Support for these amendments can be found in the original claim language and throughout the specification, as set forth below. It is believed that these amendments add no new matter. In light of these amendments and the following remarks, applicants respectfully request reconsideration of this application, entry of these amendments and allowance of the pending claims.

Attached hereto is a marked up version of the changes made to the claims and by the current amendment. The attachment is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE."**

Applicants appreciate Examiner Wilson's insights and comments made in the March 11, 2003 telephonic interview. Applicants have clarifying amendments consistent with his recommendations and believe the claims are now in condition for allowance. If Examiner Wilson has any continuing concerns, applicants invite him to call at the phone number listed below.

Rejection under 35 U.S.C. § 101

Claims 59-80 are rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility. The Office Action goes on to state that oviposited eggs as in claims 59-

65 and 77-80 are non-statutory subject matter because they are products of nature. In support of this allegation, the Office Action cites Robertson (1997, J. Reprod. Fertility, Vol. 110, pg 205-211) which teaches that oviposition encompasses depositing an egg into the infundibulum (pg 206, col. 1, 2nd para.; "Newly ovulated ova were obtained from the body cavity or the first few centimeters of the infundibulum of hens killed... ...approximately 15 minutes after oviposition"). The Office Action states that an oviposited egg encompasses an egg in the infundibulum, and an oviposited, fertilized egg in the infundibulum has the number of cells required in the claims and is a product of nature. Therefore, the oviposited eggs are non-statutory subject matter because they are a product of nature.

An "oviposited egg" refers to an avian egg in a shell, that is, an egg with a calcium carbonate shell that has been extruded from the vagina of the bird. See in the specification page 7, lines 23-25. Thus, applicants define an oviposited egg to be a laid egg, a term that is well known to a person of skill in the art. Applicants' definition of "oviposited" describes an egg that has been expelled from the vagina of an avian species. Applicants' definition of "oviposited" is consistent with literature in the field. (See Chapter 2, page 9, lines 16-17 in Johnston, S.C., "In Vitro Sperm Binding, Penetration, and Fertilization of Recently Oviposited Chicken Eggs," Thesis, Graduate School of Clemson University, December, 1998.) Moreover, the common definition of "oviposit" is to lay eggs. (See page 785 in Webster's II *New College* Dictionary, attached hereto as Exhibit A.)

Furthermore, Etches *et al.*, a reference cited by the Examiner, defines the term "oviposited" to mean a laid egg, as it is defined in the instant specification. Etches *et al.* states in the caption of Figure 4, "[t]he structure of an embryo at the time of laying illustrated as a cross-section through the embryo perpendicular to the surface of the yolk. (Emphasis added.) At this time, the embryo contains 30,000-60,000 cells and is referred to as a stage X (E-G & K) embryo." Further, Etches *et al.* states, "[t]he blastomeres in a stage X (E-G & K) embryo at oviposition are morphologically similar...." (Emphasis added.) See page 436, paragraph 2. Etches *et al.* also states, "[a]fter oviposition, embryonic development ceases until the egg is incubated." See page 436, paragraph 3. The previous statement shows that Etches *et al.* describes the cessation of embryonic development after the egg is laid, and not after the egg enters the infundibulum.

Thus, applicants' definition of the term "oviposited" is well supported in the art to mean a laid egg in a calcified shell. Therefore, a laid egg in a shell that comprises an embryo that has fewer than 30,000 cells is not found in nature and is patentable. In *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980), the Supreme Court held that microorganisms made by genetic engineering are not excluded from patent protection by 35 U.S.C. § 101. The test set down by the Court for patentable subject matter is whether the living matter is the result of human intervention.

M.P.E.P. § 2105 elaborates on the holding of *Chakrabarty*, emphasizing the following points: 1) "Guided by these canons of construction, this Court has read the term 'manufacture' in § 101 in accordance with its dictionary definition to mean 'the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery." 2) "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope. 3) The Committee Reports accompanying the 1952 [patent] act inform us that Congress intended statutory subject matter to 'include anything under the sun that is made by man.' S. Rep. No. 1979, 82d Cong. 2d Sess., 5 (1952). M.P.E.P. § 2105 points out that one of the tests set forth by the Court states "A 'nonnaturally occurring manufacture or composition of matter – a product of human ingenuity – having a distinctive name, character, [and] use' is patentable subject matter."

The claimed invention is not a product of nature. In fact, it can only be the product of manufacture either by human hand or machine. Applicants claim an oviposited egg. As used in the application, an oviposited egg is an egg with a calcium carbonate shell that has been extruded from the vagina of the bird. See in the specification, page 7, lines 23-25. It is well known in the art that a naturally fertilized, oviposited avian egg in a shell comprises an embryo comprising 30,000 to 60,000 cells. A naturally fertilized, oviposited avian egg in a shell does not have fewer than 30,000 cells. Thus, an oviposited avian egg comprising an embryo that has fewer than 30,000 or 20,000 or 10,000 cells or a zygote is not found in nature. The claimed invention can

only be made by human intervention. Thus, this rejection is not supported, and applicants respectfully request its withdrawal.

The Office Action goes on to state that the examples in the specification teach fertilizing chicken eggs after they have been laid by inserting sperm into the egg to make chicks (pg 36-37). However, the Office Action alleges that the eggs outside of the body having the number of cells as required in the claims do not meet the requirements for having a specific or substantial utility. The Office Action goes on to state that Etches *et al.*, (1997, Methods Mol. Biol., Vol. 62, pg 433-450) taught that a hen egg fertilized either naturally or by artificial insemination has an embryo containing approximately 30,000 cells when expelled from the shell gland and it contains less cells while in the native reproductive system during deposition of calcium carbonate crystals or while in the surrogate shell (see page 435 or Fig. 4 or Fig. 7). The Office Action goes on to state that using an egg outside of the body having less than 30,000 cells as claimed to make chicks is not a utility that is specific because eggs in the infundibulum having less than 30,000 cells have the same function, i.e. making avians. The Office Action states that using eggs to make avians is a general utility that is applicable to any avian egg having less than 10,000-30,000 cells, no matter where it is located. The Office Action concludes that an egg outside of the body does not have a specific utility as compared to an egg having the same function located inside the body.

Applicants maintain that the claimed invention does have a specific utility. The Office Action incorrectly implies that "specific utility" means that the claimed invention must have a utility that is different from the utility of another composition of matter. In particular, the Office Action incorrectly implies that an oviposited avian egg in a shell comprising an embryo with fewer than 30,000 cells lacks specific utility because a naturally fertilized egg comprising the same number of cells in the body of a chicken has the same utility, namely, producing live chicks. However, 35 U.S.C. § 101 requires that an invention be useful; it does not state that a composition of matter must have its own unique utility.

In explaining "specific utility," M.P.E.P. § 2107.01 (attached hereto as Exhibit B) requires an Examiner to "distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful." "For example, a statement that a composition has an unspecified 'biological activity' or that does not explain why a composition with that activity is believed to be useful fails to set forth a 'specific and substantial utility.'" M.P.E.P. § 2107.02 (attached hereto as Exhibit C). As is clear from the M.P.E.P., the "specific" standard is directed to situations where applicants fail to recite a utility that can be identified, not where the utility may exist in other compositions of matter. In the instant case, the claimed invention has several specific uses, for example, the production of live chicks or the production of early embryos in eggs that can be genetically manipulated. See in the specification page 25, lines 17-20. The Utility Examination

Guidelines, effective as of January 5, 2001, do not state that a composition of matter lacks specific utility because the function of the composition may be the same as another composition found in nature. Thus, the rejection under 35 U.S.C. § 101 as lacking a specific utility should be withdrawn.

To further demonstrate that the recited utilities are specific, applicants point out that the Utility Guidelines state, for example, that an isolated or purified nucleic acid can be patentable even though the nucleic acid exists in nature in a chromosome. See Comment 2, attached hereto as Exhibit D. The specific utility of the isolated or purified nucleic acid, i.e., to encode a protein, is the same as the utility of the naturally occurring nucleic acid that is in a chromosome. However, isolated or purified nucleic acids have specific utility and are patentable. By analogy, an oviposited avian egg that is a unique composition of matter has specific utility even if it has a utility that is the same as a naturally fertilized laid egg. Thus, it is not necessary for a patentable composition of matter to have a utility that is unique and different from another composition of matter, and the rejection under 35 U.S.C. § 101 should be removed.

In another example, the Utility Guidelines point to an early patent of adrenaline to show that a composition that is isolated and/or purified by man and that has the same utility as the composition found in nature is patentable. See Comment 2, attached hereto as Exhibit D. The court held that compositions isolated from nature are patentable. The court stated that "even if it were merely an extracted product without change, there is no rule that such products are not

patentable." (Parke-Davis & Co. v. H. K. Mulford Co., 189 F.95, 103 (S.D.N.Y. 1911)). Thus, even though the utility of a purified adrenaline that can be administered to a subject is the same as the utility of naturally occurring adrenaline produced in a subject, the court held that the purified composition was patentable.

As noted by the Office Action, one specific utility of the egg of the claimed invention and the specific utility of a naturally fertilized egg are the same, i.e., the production of a live bird. Thus, the Office Action admits there is a utility that one can point to in the application. Moreover, just as an isolated nucleic acid that is novel is patentable even though its specific utility is the same as the specific utility of the naturally occurring nucleic acid in a chromosome, and just as a purified adrenaline composition was patentable even though its specific utility is the same as the specific utility of naturally occurring adrenaline in a subject, so too is the novel egg of the claimed invention patentable even though one of its specific utilities is the same as the specific utility of a naturally fertilized egg.

In addition to the specific utility of producing live chicks, applicants respectfully assert that the claimed invention has additional specific, substantial and credible utilities, for example, the production of live transgenic chicks and/or the production of early embryos in an egg that can be genetically manipulated. See in the specification page 25, line 25 through page 29, line 7. In summary, because applicants' discovery allows one access to large numbers of early embryos that do not require re-introduction into the female or complicated *ex vivo* incubation, it is useful

as a platform to make and study chicken transgenics. Because applicants do disclose a practical or real world benefit available from the invention, i.e., a specific, substantial and credible utility, applicants believe that this rejection based on lack of utility is unwarranted and respectfully request that this rejection be withdrawn.

The Office Action goes on to state that claims 66-74 are directed toward an oviposited avian or chicken egg comprising a native embryo having fewer than 30,000 cells, wherein the embryo can develop into a live chick, and wherein the egg shell has an opening less than 4 cm; claims 75 and 76 are directed toward an oviposited chicken egg comprising a zygote, wherein the zygote can develop into a live chick, and wherein the egg shell has an opening of less than 4 cm. The Office Action alleges that claims 66-74 lack utility for reasons cited above and because an egg having a window does not have a specific utility. The Office states that a window does not confer any function to the egg that is different than an egg without a window and that the window does not alter the avian produced from the egg. The Examiner concludes that an egg having a window as claimed does not have a utility that is specific as compared to an egg that does not have a window.

For the reasons stated above, the Office Action's allegation is not supported. To satisfy the use requirement of 35 U.S.C. § 101, applicant need only provide one specific, substantial and credible use for the claimed invention. Applicant has no burden to show that the utility of the claimed invention differs from the utility of another composition.

Applicants respectfully point out that the Office Action incorrectly interprets the requirement of 35 U.S.C. § 101 by focusing on the chick produced by the egg, rather than focusing on the utility of the egg itself. Whereas a specific utility for the opening need not be set forth, if the egg itself has a utility, in this embodiment of the invention, an opening of less that 4 centimeters has a specific use. For example, the opening allows for the production of a live chick from an oviposited, unfertilized egg, providing access to the developing embryo for the purposes of gene transfer to make a transgenic chick, or vaccinating the early embryo. Applicants believe that an additional specific utility of an oviposited avian egg in a shell, comprising an embryo having fewer than 30,000 cells, 20,000 cells, 10,000 cells, or a zygote, wherein the embryo can develop into a live chick and wherein the egg shell has an opening less than 4 centimeters is for the use in producing a transgenic chick. Applicants believe that this rejection based on lack of utility is unwarranted and respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 59-80 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Office Action states that the examples in the specification teach fertilizing chicken eggs after they have been laid by inserting sperm into the egg to make chicks (pg 36-37). The Office states that the purpose of the eggs claimed is to make avians. The Office goes on to state that the enablement rejection set forth below is based on how to use the eggs claimed to make avians -the sole disclosed purpose for the eggs claimed. The Office Action states that the prior art did not teach successfully fertilizing avian eggs outside of the body or obtaining an embryo in such manner that an avian was produced and then concludes, "therefore, it was unpredictable how to obtain such eggs."

The Office Action seems to have rejected the claims on the basis that if the claims lack utility, they cannot teach how to use the invention. However, applicants have shown that the invention satisfies 35 U.S.C. § 101, and, thus, the associated rejection under 35 U.S.C. § 112 should be withdrawn.

In addition, the examples in the specification teach how to practice the invention. For example, in Example 1, 43 freshly laid unfertilized eggs were selected; sperm was delivered into the eggs using the disclosed method; and the eggs were incubated. Ten days later, routine candling, well known to one skilled in the art, was used to determine which eggs were fertilized. Thirty-five eggs were fertilized. Of the 35 fertilized oviposited eggs in a shell, 32 were successfully brought to hatching, and all but one of the chicks were healthy. Thus, 72% of the 43 oviposited eggs treated by a fertilization method disclosed in the specification produced a

healthy live chick. Further, over 90% (32 of 35) of the oviposited fertilized avian eggs in a shell made by a disclosed method produced a healthy chick. Example 3 also sets forth a method of making the claimed invention.

The Office Action states that Etches *et al.* (1997, *Methods Mol. Biol.*, Vol. 62, pg 433-450) taught that a hen egg fertilized either naturally or by artificial insemination has an embryo containing approximately 30,000 cells when expelled from the shell gland and it contains less cells while in the native reproductive system during deposition of calcium carbonate crystals or while in the surrogate shell (see page 435 or Fig. 4 or Fig. 7). The Office concludes that using an oviposited egg having less than 30,000 cells as claimed to make chicks is not an enabled use that is specific to such an egg because a non-oviposited egg having less than 30,000 cells have the same structure and function and are used to make chicks.

The Office errs when it states that "using an oviposited egg having less than 30,000 cells as claimed to make chicks is not an enabled use that is specific to such an egg because a non-oviposited egg having less than 30,000 cells have the same structure and function and are used to make chicks." By definition, the claimed invention does not have the same structure as a non-oviposited egg. An "oviposited egg" refers to an avian egg in a shell, that is, an egg with a calcium carbonate shell that has been extruded from the vagina of the bird. This definition particularly points out that the laid egg has a calcified shell and that these claims are different from an egg that lacks a calcified shell that is traveling through the female bird's oviduct and is

non-oviposited. Because the Office has made a rejection based on an incorrect assumption, applicants respectfully request that this rejection be withdrawn.

In summary, the Office Action seems to have rejected the claims on the basis that if the claims lack utility, they cannot teach how to use the invention. However, applicants have shown that the invention satisfies 35 U.S.C. § 101, and, thus, the associated rejection under 35 U.S.C. § 112 should be withdrawn.

The Office Action goes on to state that using the eggs claimed to make avians is a general use that is applicable to any avian egg having less than 30,000 cells, no matter where it is located. The Office Action further states that the location of the egg (i.e., oviposited) does not render the egg claimed as having a specific utility as compared to other eggs having the same function. The Office concludes that the specification does not provide an enabled use for the eggs claimed fertilized outside of the body that is specific to such eggs.

As stated above in response to the utility rejection based on 35 U.S.C. § 101, the Office Action incorrectly implies that the term "specific use" means that a claimed invention must have a use that is unique and that no other composition of matter can share that same use. Moreover, as pointed out above, the claimed invention has a specific, substantial and credible utility, for example, for producing a live chick and/or for producing a transgenic bird. Therefore, for the

same reasons offered in response to the rejection based on 35 U.S.C. § 101, applicants believe that this rejection should be withdrawn.

The Office Action further states that the specification does not provide an enabled use for oviposited eggs having an opening less than X cm/mm that is specific to such eggs. The Office further states that eggs having an opening have the same function as those not having an opening -to make chicks -which is general and applicable to any avian egg no matter what size opening it has. The Office then goes on to state that such an egg may not function to produce a chick because the claim does not require the opening is sealed; therefore, eggs having an opening as claimed do not have an enabled use in the disclosure that is specific to such eggs.

Applicants teach that an oviposited avian egg in a shell comprising an embryo having fewer than 30,000 cells, or 20,000 cells, or 10,000 cells, or a zygote, wherein the embryo can develop into a live chick and wherein the egg shell has an opening less than 4 centimeters has a specific utility. The claimed invention can be used to produce birds, as the opening is the means to deliver sperm. The invention can also produce transgenic birds. For example, "[t]he transducing particles can be administered directly to the oviposited egg comprising the early avian embryo using the methods described herein. For example, a window can be generated just above the embryo and transducing particles introduced into the subgerminal cavity of the embryo. The window is then sealed, and the eggs are placed into incubators for development." See in the specification page 26, line 27 through page 27, line 3. Thus, in addition to producing

avians via the opening, a person of skill can deliver to the embryo the transducing particles through the opening in the shell as claimed.

With regard to the issue in the Office Action that the egg "may not function to produce a chick because the claim does not require the opening is sealed and therefore eggs having an opening as claimed do not have an enabled use in the disclosure that is specific to such eggs," applicants respectfully point out that a person of skill would know that it is customary to seal an opening in a shell to prevent loss of the embryo. Thus, the claim does not exclude that the opening will ultimately be sealed. Further, the specification defines the term "opening" to mean that "a hole has been made in the egg at some point after oviposition. 'Opening' includes an egg where the hole has subsequently been sealed. For example, an egg having a hole created by a needle used to inject a sample and then sealed is, even after sealing, within the definition of avian egg having an opening." See in the specification, page 12, lines 22-25. Applicants, therefore, believe that this rejection is unwarranted and respectfully request that it be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 59-80 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action states that while applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F .2d 367, 73 USPQ 482 (CCPA 1947). The

Office Action goes on to state that the term "oviposited" in the claims is used to mean eggs "extruded from the vagina" (pg 5, line 25; pg 7, line 25), while the art at the time of filing used the term to describe an egg deposited into the infundibulum (Robertson, 1997, J. Reprod. Fertility, Vol. 110, pg 205- 211; pg 206, col. 1, 2nd para.; "Newly ovulated ova were obtained from the body cavity or the first few centimeters of the infundibulum of hens killed... ...approximately 15 minutes after oviposition."). The Office Action concludes that the term "oviposited" eggs cannot be limited to eggs extruded from the vagina as defined in the specification.

Applicants' use of "oviposited" is not repugnant to the usual meaning of that term. Although "oviposited" can be used inconsistently in the art cited in the Office Action to mean either "ovulated," i.e., released from the follicle, or "an egg with a calcium carbonate shell that has been extruded from the vagina of the bird," applicants have clearly limited the definition to mean "an egg with a calcium carbonate shell that has been extruded from the vagina of the bird." See in the instant specification page 7, lines 24-25. As noted above, the cited art describes "oviposited" as an egg that has been expelled from the vagina of an avian species. (See Chapter 2, page 9, lines 16-17 in Johnston, S.C., "In Vitro Sperm Binding, Penetration, and Fertilization of Recently Oviposited Chicken Eggs," Thesis, Graduate School of Clemson University, December, 1998.) Moreover, the common definition of "oviposit" is to lay eggs. (See page 785 in Webster's II *New College* Dictionary, attached hereto as Exhibit A.)

Furthermore, Etches *et al.*, a reference cited in the Office Action, defines the term "oviposited" to mean a laid egg, as it is defined in the instant specification. Specifically, Etches *et al.* states in the caption of Figure 4, "[t]he structure of an embryo at the time of laying illustrated as a cross-section through the embryo perpendicular to the surface of the yolk. (Emphasis added.) At this time, the embryo contains 30,000-60,000 cells and is referred to as a stage X (E-G & K) embryo." Further, Etches *et al.* states, "[t]he blastomeres in a stage X (E-G & K) embryo at oviposition are morphologically similar...." (Emphasis added.) See page 436, paragraph 2. Etches *et al.* also states, "[a]fter oviposition, embryonic development ceases until the egg is incubated." See page 436, paragraph 3. The previous statement shows that Etches *et al.* describes the cessation of embryonic development after the egg is laid, and not after the egg enters the infundibulum.

Thus, applicants' use of "oviposited" is not repugnant to the common meaning, and this basis of rejection should be removed.

The Office Action states that the term "native" is indefinite because it is a relative term, is not adequately defined in the specification and the claim does not state to what the embryo or yolk is native. The Office Action acknowledges that the specification defines the term "native" as "growing, living or produced in its place of origin. Thus, a native embryo is an embryo that develops and hatches in the same shell in which the female pronucleus was formed." The Office Action then states that such a conclusion cannot be made based on the definition provided and

that any embryo living in a shell is an embryo "growing, living or produced in its place of origin" because it is in a living shell -its place of origin. The Office Action goes on to state that the specification does not limit a "native embryo" to an embryo "that develops and hatches in the same shell in which the female pronucleus was formed"; it is merely an example. The Office Action concludes that the definition does not limit a "native" embryo or yolk to an embryo or yolk growing, living or produced in its shell of origin.

As recommended by the Examiner in the March 11, 2003 interview, claims 59, 64, 65 and 78-80 are amended herein by deleting the term "native" and substituting therefor a clause that more clearly defines the invention. For example, amended claim 59 recites, "[a]n oviposited avian egg comprising a shell and an embryo that develops and hatches in the shell that formed around a female pronucleus that developed into the embryo, wherein the embryo has fewer than 30,000 cells and can develop into a live chick." In another example, claim 78 recites "[a]n oviposited chicken egg comprising a yolk in a shell that formed around the yolk during shell membrane deposition and calcification and an embryo having fewer than 30,000 cells, wherein the embryo can develop into a live chick." Support can be found in the instant specification on pages 5-6; page 7, lines 19-27; page 8, lines 1-6; page 11, lines 25-28; page 12, line 1 to page 13, line 4. Applicants believe that these rejections based on indefiniteness are overcome and respectfully request that these rejections be withdrawn.

The Office Action states that the phrase "the egg shell" in claims 66 and 73-76 lacks antecedent basis. However, the claims state that the egg has been oviposited. In the specification, applicants define "oviposited" to be "an egg with a calcium carbonate shell that has been extruded from the vagina of the bird." See in the specification page 7, lines 23-25. Thus, oviposited avian egg provides antecedent basis and the claims need not be amended. Therefore, applicants respectfully request that these rejections be withdrawn and that claims 66 and 73-76 be allowed.

Rejection under 35 U.S.C. § 102

Applicants note that the Office Action acknowledges that "[t]he prior art did not teach successful fertilizing avian eggs outside of the body or obtaining an embryo in such a manner such that an avian was produced." See page 6, last paragraph, first sentence of the Action.

A. Nevertheless, claims 59-80 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Tanaka *et al.* (1994, J. Reprod. Fert., Vol. 100, pg 447-449). The Office Action states that Tanaka *et al.* taught a laid egg comprising a freshly fertilized ovum (pg 447, col. 2, "Materials and Methods;" pg 448, Fig. 1) made transferring a day old fertilized ovum into the birth canal of the chicken. The Office also states that a shell formed around the ovum as it passed through the recipient hen' s reproductive system, the egg was laid on the day following the transfer (pg 448, col. 1 line 4) and a chick hatched (pg 448, col. 2, first full para., line 9).

The Office goes on to state that the day old fertilized ovum had less than 10,000 cells as claimed because a zygote is one cell.

The Office Action further states that "native" is defined as growing, living or produced in its place of origin and that the specification concludes, "[t]hus, a native embryo is an embryo that develops and hatches in the same shell in which the female pronucleus was formed. Thus, the embryo is descended from the native ovum" (pg 11, line 27 to pg 12, line 3). The Office Action goes on to state that the embryo in the egg taught by Tanaka *et al.* is a "native embryo" because it is growing in its place of origin -a shell -and because it is descended from the native ovum and that the definition of a "native embryo" is not limited to an embryo that develops and hatches in the same shell in which the female pronucleus was formed. The Office Action states that for these reasons, claims 64, 65 and 78-80 have been included; claims 66-76 are included because "the egg shell" lacks antecedent basis (see 112/2nd); and claim 77 is included because the egg produced by the method of claim 9 has the same structure and function as the egg taught by Tanaka *et al.*

As suggested by the Examiner, applicants have amended claims 59, 64, 65, and 78-80 herein by deleting the term "native" to clarify what was meant by "native" by adding specific language to the claims.

Tanaka *et al.* teaches that an unfertilized ovum, removed from a donor hen, can be fertilized *in vitro* and then transferred after about 15 minutes into the infundibulum (upper part of a hen's reproductive tract) of a recipient hen and then migrate down the tract over a day's time to be laid in a shell (developed in the recipient hen) and then incubated to produce a live chick. The term "oviposited" as used in Tanaka *et al.* clearly means "ovulated." "This study demonstrated that fertile eggs can be obtained by IVF of ova removed shortly after ovulation and subsequently transplanted into the oviduct of recipient hens." See page 448, 'Discussion,' first sentence.

Moreover, it is clear that the laid, fertilized egg in a shell in Tanaka *et al.* traveled the length of the oviduct in the recipient hen and that the approximate 24 hours that the egg traveled through the oviduct was the same time that a naturally fertilized egg in a hen would take to travel to the vagina to be oviposited (laid). Thus, as is well known in the art, the laid egg in Tanaka *et al.* had at least 30,000-60,000 cells. In contrast, the claimed invention comprises an embryo having fewer than 30,000 cells.

Further, the Office Action misreads the reference when it alleges that Tanaka *et al.* taught an egg that "had less than 10,000 cells as claimed because a zygote is one cell." In fact, Tanaka *et al.* showed that a zygote made by *in vitro* fertilization could be transferred into the infundibulum of a recipient hen and then develop into an embryo as it traveled down the oviduct. The zygote was not in a laid egg in a calcified shell; rather, it was in the upper part of a hen

oviduct. Then, by the time the egg of Tanaka *et al.* was actually laid, it would contain over 30,000 cells. Thus, Tanaka *et al.* cannot anticipate the claims.

Tanaka *et al.* does not teach an oviposited avian egg comprising a shell and an embryo that develops and hatches in the shell that formed around a female pronucleus that developed into the embryo, wherein the embryo has fewer than 30,000 cells and can develop into a live chick. Thus, claims 59-65 are not anticipated. Moreover, Tanaka *et al.* does not teach an oviposited egg comprising an embryo having fewer than 30,000 or 20,000 or 10,000 cells or a zygote, wherein the shell has an opening. Thus, claims 66-76 are not anticipated. Moreover, because Tanaka *et al.* does not teach an oviposited chicken egg comprising a yolk in a shell that formed around the yolk during shell membrane deposition and calcification and an embryo having fewer than 30,000 cells, wherein the embryo can develop into a live chick, claims 78-80 are not anticipated.

Claim 77 is amended herein to recite "[a]n oviposited egg comprising a zygote, produced by fertilizing an ovum by delivering a sperm sample comprising avian sperm in a physiologically acceptable carrier into the egg and incubating the egg." Tanaka *et al.* does not teach a laid egg comprising a zygote; therefore, the egg taught by Tanaka *et al.* does not have the same structure as the claimed invention. For all the reasons stated above, applicants believe that these rejections are overcome and respectfully request that these rejections be withdrawn and that claims 59-80 be allowed.

B. Claims 59-80 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Johnston (1998, Poultry Science, Vol. 77, pg 142). The Office Action states that Johnston taught a fertilized oocyte (6 lines from the bottom) which is equivalent to the eggs claimed. The Office Action states that the egg used for fertilization is oviposited (line 9) and that a fertilized oocyte is equivalent to an embryo or zygote, and is less than 10,000 cells as claimed because it is one cell that proliferates (last sentence). The Office Action further states that the fertilized oocyte is a "native" embryo or zygote because it is growing and living "in its place of origin" as defined in the specification (pg 11, line 27). The Office Action states that while an example of a "native embryo" is an embryo that develops and hatches in the same shell in which the female pronucleus was formed (sentence bridging pg 11-12), embryos/zygotes do not have to be maintained in a shell, the definition of "native" embryos/zygotes is not limited to embryos/zygotes in shells, or in the same shell in which the female pronucleus was formed. The Office Action goes on to state that claims 66-76 are included because "the egg shell" lacks antecedent basis (see 112/2nd) and that claim 77 is included because the egg produced by the method of claim 9 has the same structure and function as the egg taught by Johnston.

As suggested by the Examiner, applicants have amended claims 59, 64, 65, and 78-80 herein by deleting the term "native" to clarify what was meant by "native" by adding specific language to the claims.

Johnston *et al.* teaches that an oocyte removed from a recently oviposited (laid) unfertilized avian egg can be fertilized *in vitro*, and, in some cases, the fertilized oocyte can show evidence of cellular proliferation. Johnston *et al.* did not teach the claimed invention, i.e., an oviposited avian egg comprising a shell and an embryo that develops and hatches in the shell that formed around a female pronucleus that developed into the embryo, wherein the embryo has fewer than 30,000 cells and can develop into a live chick. Thus, claims 59-65 are not anticipated. Moreover, Johnston *et al.* does not teach an oviposited egg comprising an embryo having fewer than 30,000 or 20,000 or 10,000 cells or a zygote, wherein the shell has an opening. Thus, claims 66-76 are not anticipated. Further, because Johnston *et al.* does not teach an oviposited chicken egg comprising a yolk in a shell that formed around the yolk during shell membrane deposition and calcification and an embryo having fewer than 30,000 cells, wherein the embryo can develop into a live chick, claims 78-80 are not anticipated.

Claim 77 is amended herein to recite "[a]n oviposited egg comprising a zygote, produced by fertilizing an ovum by delivering a sperm sample comprising avian sperm in a physiologically acceptable carrier into the egg and incubating the egg until hatching." Johnston *et al.* does not teach a laid egg comprising a zygote; therefore, the egg taught by Johnston *et al.* does not have the same structure as the claimed invention. For all the reasons stated above, applicants believe that these rejections are overcome and respectfully request that these rejections be withdrawn and that claims 59-80 be allowed.

C. Claims 59-80 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Perry (1988, Nature, Vol. 331, pg 70-72). The Office Action states that Perry taught a fertilized oocyte recovered from the oviduct of a hen surrounded by a capsule of dense, viscous albumen (pg 71, Fig. 1A caption). The Office Action states that the egg is "oviposited" because it is present in the infundibulum and also because it is removed from the body. The Office Action goes on to state that the fertilized oocyte is "native" because it is maintained in its capsule of albumen (Fig. 1B). The Office Action further states that the embryo taught by Perry is a "native embryo" because it is descended from the native ovum (pg 12, line 1) and that the definition of "native" embryos/zygotes is not limited to embryos/zygotes in the same shell in which the female pronucleus was formed (sentence bridging pg 11-12). The Office Action states that Perry also taught the embryos develop into live chicks (pg 72, Table 1; last column, third row). The Office Action states that claims 66-76 are included because "the egg shell" lacks antecedent basis (see 112/2nd) and that claim 77 is included because the egg produced by the method of claim 9 has the same structure and function as the egg taught by Perry; thus, Perry anticipates the claims.

As suggested by the Examiner, applicants have amended claims 59, 64, 65, and 78-80 herein by deleting the term "native" to clarify what was meant by "native" by adding specific language to the claims.

Perry teaches removing a fertilized oocyte from the oviduct of a hen and transferring this oocyte into a series of different shells containing culture medium and incubating the embryos. This fertilized avian embryo, transferred into a series of shells that are not produced by the embryo as it travels through a hen's oviduct, is not the claimed invention. Perry does not teach an oviposited avian egg comprising a shell and an embryo that develops and hatches in the shell that formed around a female pronucleus that developed into the embryo, wherein the embryo has fewer than 30,000 cells and can develop into a live chick. Thus, claims 59-65 are not anticipated. As noted elsewhere herein, oviposited is an egg with a calcium carbonate shell that has been extruded from the vagina of the bird. See in the specification page 7, lines 23-25. Moreover, Perry does not teach an oviposited egg comprising an embryo having fewer than 30,000 or 20,000 or 10,000 cells or a zygote, wherein the shell has an opening. Thus, claims 66-76 are not anticipated. Moreover, because Perry does not teach an oviposited chicken egg comprising a yolk in a shell that formed around the yolk during shell membrane deposition and calcification and an embryo having fewer than 30,000 cells, wherein the embryo can develop into a live chick, claims 78-80 are not anticipated.

Claim 77 is amended herein to recite "[a]n oviposited egg comprising a zygote, produced by fertilizing an ovum by delivering a sperm sample comprising avian sperm in a physiologically acceptable carrier into the egg and incubating the egg until hatching." Perry does not teach a laid egg comprising a zygote; therefore, the egg taught by Perry does not have the same structure as the claimed invention. For all the reasons stated above, applicants believe that these

rejections are overcome and respectfully request that these rejections be withdrawn and that claims 59-80 be allowed.

Rejection under 35 U.S.C. § 103

Claims 59-80 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Tanaka (1994, J. Reprod. Fert., Vol. 100, pg447-449), Johnston (1998, Poultry Science, Vol. 77, pg 142), or Perry (1988, Nature, Vol. 331, pg 70-72) in view of Goldberg (1992, Ped. Research, Vol. 32, pg 23-26). The Office Action states that Tanaka, Johnston and Perry taught an oviposited avian egg having less than 10,000 cells as claimed (see 102 rejections above). The Office Action admits that Tanaka, Johnston and Perry did not teach making a window less than 5 mm as claimed. The Office Action goes on to state that Goldberg taught making a 1 mm window in avian eggs having embryos to inject various solutions (para. bridging pg 23-24).

The Office Action concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to obtain an oviposited avian egg having less than 10,000 cells as taught by Tanaka, Johnston or Perry and make a 1 mm window in the egg as taught by Goldberg. The Office Action goes on to state that one of ordinary skill in the art at the time of the invention would have been motivated to inject various solutions into the eggs of Tanaka, Johnston or Perry to study the effects of teratogenic compounds on avian embryos having less than 10,000 cells. The Office Action further concludes that one of ordinary skill in the art at the time of the invention would have been motivated to use the eggs of Tanaka,

Johnston or Perry in teratogenic studies to determine if manipulating eggs as taught by Tanaka, Johnston or Perry effect teratogenesis; thus, applicants' claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

None of the cited references, alone or in combination, suggests a) an oviposited avian egg comprising a shell and an embryo that develops and hatches in the shell that formed around a female pronucleus that developed into the embryo, wherein the embryo has fewer than 30,000 cells and can develop into a live chick; b) an oviposited chicken egg comprising a yolk in a shell that formed around the yolk during shell membrane deposition and calcification and an embryo having fewer than 30,000 cells, wherein the embryo can develop into a live chick; or c) an oviposited egg comprising a zygote produced by fertilizing an ovum by delivering a sperm sample comprising avian sperm in a physiologically acceptable carrier into the egg and incubating the egg. Further, in Tanaka *et al.*, the eggs at the time of laying (oviposition) had the same number of cells that a naturally fertilized avian egg that is laid after traveling down the oviduct of the hen in which it is fertilized, namely 30,000 to 60,000 cells. Similarly, Johnston *et al.* teaches limited success in obtaining fertilization and only achieved the limited success after the outer perivitelline membrane and ovalbumen were removed. Further, Johnston *et al.* teaches fertilization *in vitro* after the oocyte was removed from its shell. The fertilized oocyte was shown only to have some cellular proliferation and never developed into an embryo that can develop into a live chick. Perry taught *in vitro* fertilization of an ovum and transferring the developing embryo into a series of shells during incubation. Further, Goldberg *et al.* taught

making an opening in the shell of naturally fertilized eggs after the eggs were laid. As well known in the art, the eggs in Goldberg *et al.* thus must comprise embryos having 30,000 to 60,000 cells and are not the eggs of the claimed invention.

Further, the Office Action concedes that prior to this application, unpredictable results were likely if one tried to produce an oviposited egg in a shell comprising such an early stage embryo. "The prior art did not teach successful fertilizing avian eggs outside of the body or obtaining an embryo in such a manner that an avian was produced. Therefore, it was unpredictable how to obtain such eggs." See page 6, last paragraph, Office Action. Because the prior art teaches that producing the claimed invention would be unpredictable, the present invention cannot be obvious. Likewise, none of the cited references motivates a person of skill to make the claimed eggs having an opening of less than four centimeters or one centimeter. Specifically, in the absence of applicants' method, one would not have been able to make an early embryo in an egg in which only a limited size opening had been made. Thus, claims 66-76 are further not obvious. Therefore, applicants respectfully request that this rejection be withdrawn and that claims 59-80 be allowed.

Double Patenting

Claims 59-80 of this application are alleged to conflict with claims of Application No. 09/784,803. During prosecution of Application Serial No. 09/784,803, the aforementioned conflicting claims were withdrawn from prosecution. Therefore, this rejection is rendered moot.

ATTORNEY DOCKET NO. 23101.0003U1
Serial No. 09/784,575

Therefore, applicants respectfully request that this rejection be withdrawn and that claims 59-80 be allowed.

A Credit Card Payment Form PTO-2038 authorizing payment in the amount of $205.00 for a two (2) month extension of time fee and a Request for Extension of Time are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

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Via Facsimile Transmission

I hereby certify that this correspondence is being sent via facsimile transmission addressed to Examiner M. Wilson at (703) 308-4242, Group Art Unit 1632, Commissioner for Patents, Alexandria, VA 22313-1450 on the date shown below.

David G. Perryman — 3-31-03 Date

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Claims 59, 64, 65 and 77-80 have been amended as follows:

59. (Amended) An oviposited avian egg comprising a [native] shell and an embryo that develops and hatches in the shell that formed around a female pronucleus that developed into the embryo, wherein the embryo has [having] fewer than 30,000 cells[, wherein the embryo] and can develop into a live chick.

64. (Amended) An oviposited chicken egg comprising a [native] shell and an embryo that develops and hatches in the shell that formed around a female pronucleus that developed into the embryo, wherein the embryo has [having] fewer than 30,000 cells[, wherein the embryo] and can develop into a live chick.

65. (Amended) An oviposited chicken egg comprising a [native] shell and a zygote that develops and hatches in the shell that formed around a female pronucleus that developed into the zygote.

77. (Amended) An oviposited egg comprising a zygote produced by [the method of claim 9, wherein the egg comprises a zygote] fertilizing an ovum by delivering a sperm sample comprising avian sperm in a physiologically acceptable carrier into the egg and incubating the egg.

78. (Amended) An oviposited chicken egg comprising a [native] yolk in a shell that formed around the yolk during shell membrane deposition and calcification and an embryo having fewer than 30,000 cells, wherein the embryo can develop into a live chick.

79. (Amended) An oviposited chicken egg comprising a [native] yolk in a shell that formed around the yolk during shell membrane deposition and calcification and an embryo having fewer than 20,000 cells, wherein the embryo can develop into a live chick.

80. (Amended) An oviposited chicken egg comprising a [native] yolk in a shell that formed around the yolk during shell membrane deposition and calcification and an embryo having fewer than 10,000 cells, wherein the embryo can develop into a live chick.